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TAGS: ETRD KIPR USTR TU
SUBJECT: TURKEY: DANISH COMPANY COULD BE FIRST TO SUFFER DE CASUALTY

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¶1. (SBU) Summary: According to Istanbul-based U.S. pharmaceutical company reps, a Danish pharmaceutical company may be the first to have a generic application approved in Turkey for a product approved in the EU after January 1, 2001 and in Turkey after January 1, 2005, for which they believe the period of data protection has not yet expired. The facts in the case are not clear yet, but the EU has sent the Turkish MOH a "strongly worded letter" encouraging them not to approve such generic applications, of which the industry believes there are approximately 35. We will coordinate a meeting with our EU counterparts to discuss this with the MOH and urge them to meet their obligations. End summary.

¶2. (SBU) According to Istanbul-based U.S. pharmaceutical company reps, Danish pharmaceutical company Lundbeck may incur the first data exclusivity casualty as it is rumored that generic applications to market copies of one of their molecules recently received marketing approval by the Ministry of Health. The product in question was approved in the EU after January 1, 2001, but one dosage was given marketing approval in Turkey in 2003 and two more dosages did not receive marketing approval in Turkey until the middle of 2005. According to Turkish regulations, unless the generic companies submitted their own complete dossiers for consideration (which would include chemical composition and clinical trial information), generic applications cannot rely on the data of research-based companies that received marketing approval for a molecule after January 1, 2005. Therefore, under Turkey's data-exclusivity regulations, the Lundbeck molecule dosages that were approved in Turkey in 2005 should receive data protection for six years from the date of approval in the EU, which is until some point in 2007.

¶3. (SBU) Pharmaceutical company reps assume, but it has not yet been confirmed, that the generic applications rely on the data supplied in Lundbeck's complete application to the MOH. Dossier information including

clinical trials and chemical composition are easily obtained on the Internet or in medical periodicals. The Lundbeck molecule in question was one of the 35 (reftel) for which the MOH could not guarantee data exclusivity because (assumedly) generic applications had been filed for the drug prior to January 1, 2005.

¶4. (SBU) Officials at the EU mission in Ankara told us that the EU sent another "strongly worded" letter to Turkey last week encouraging them not to go through with their plans to approve the generic applications for the Lundbeck molecule. The European pharmaceutical industry has suggested referring this case to the EU's DG for Enlargement and making data exclusivity a benchmark for the free movement of goods chapter during Turkey's EU accession process. U.S. pharmaceutical companies support this proposal.

¶5. (SBU) According to local PhRMA company reps, they are considering submitting to the USG a petition to rescind Turkey's GSP privileges until it implements better protection for confidential data. They told us that in a recent conference call, PhRMA companies decided to wait until May so that the Lundbeck case could play out. They asked, however, that the Embassy consider a joint approach to MOH officials with local EU representatives in the near future to express our concern about the case. As with other DE-related cases, however, they asked that we protect the identity of the company in question.

¶6. (SBU) Comment: While the facts in the Lundbeck case are not yet clear, we are concerned about the possibility that generic applications for one of the 35 molecules in question could have been approved prior to the expiration of its data exclusivity period. We support the idea of a combined effort with our EU

counterparts in Ankara, who have also expressed their interest in coordinating efforts on this subject. We should urge Turkey to uphold its obligations under its current IPR legislation. Too many times, local PhRMA companies argue about Turkey's requirements under TRIPS and their delay in implementing IPR protection. While we agree with this and continue to push the GOT to become fully TRIPS compliant, the pharmaceutical companies begrudgingly agreed to the existing regulation in order to implement data protection in Turkey. The GOT does not respond to the argument that they provided too little too late and should be reminded of their obligations under their existing regulations. End comment.

WILSON